BTL vac

USER'S MANUAL

v110z7IE25/01/2006EN

Before You Start

This manual has been written for the owners and operators of the vacuum unit BTL vac. It contains general instructions on operation, precautionary practices and maintenance. While we would like you to start using your equipment right away, we encourage a thorough reading of this manual in order to fully understand the operational features of your product.

All of us at BTL wish you every success with this product. We pride ourselves on being as responsive as possible to our customer's needs. Your suggestions and comments are always welcome since we believe an ongoing relationship with our customers is critically important to our future product line. Please call us or email us your suggestions.

Please remember to complete the warranty registration form printed in this manual. The warranty form should be returned to us no later than 30 days following installation of your equipment to initiate warranty protection.

Again, thanks for being a BTL customer. In the event of a problem, or if you require service, please make an initial call to your local distributor, who will decide whether to refer the problem to our office.

CONTENTS

1 GENERAL CHARACTERISTICS 4

2 INSTRUCTIONS FOR USE 5

2.1 Front View 5
2.2 Rear View 6
2.3 Assembly and Putting into Operation 7
2.4 Interconnection with Electrotherapy Devices 8
2.4.1 Connecting BTL vac to BTL-5000 8
2.4.2 Connecting BTL vac to BTL-06 8
2.4.3 Connecting BTL vac to Other Electrotherapy Devices 8
2.5 Operation 8
2.5.1 Suction Cup Electrodes 9
2.5.2 Water Container 9
2.5.3 Changing Vacuum Pressure 9
2.5.3.1 Continuous Mode 9
2.5.3.2 Pulse Modes 15, 30, 45, 60 9
2.5.3.3 Massage Programs 1, 2, 3, 4 9
2.5.3.4 Controlling Vacuum Pressure by BTL-5000 9
2.5.4 Washable Plate 9
2.6 Accessories 10
2.6.1 Basic Accessories 10
2.6.2 Optional Accessories 10

3 MAINTENANCE AND SAFETY 11

3.1 Safety 11
3.2 Useful addresses 13
3.3 Warranty 13

4 TECHNICAL PARAMETERS 14

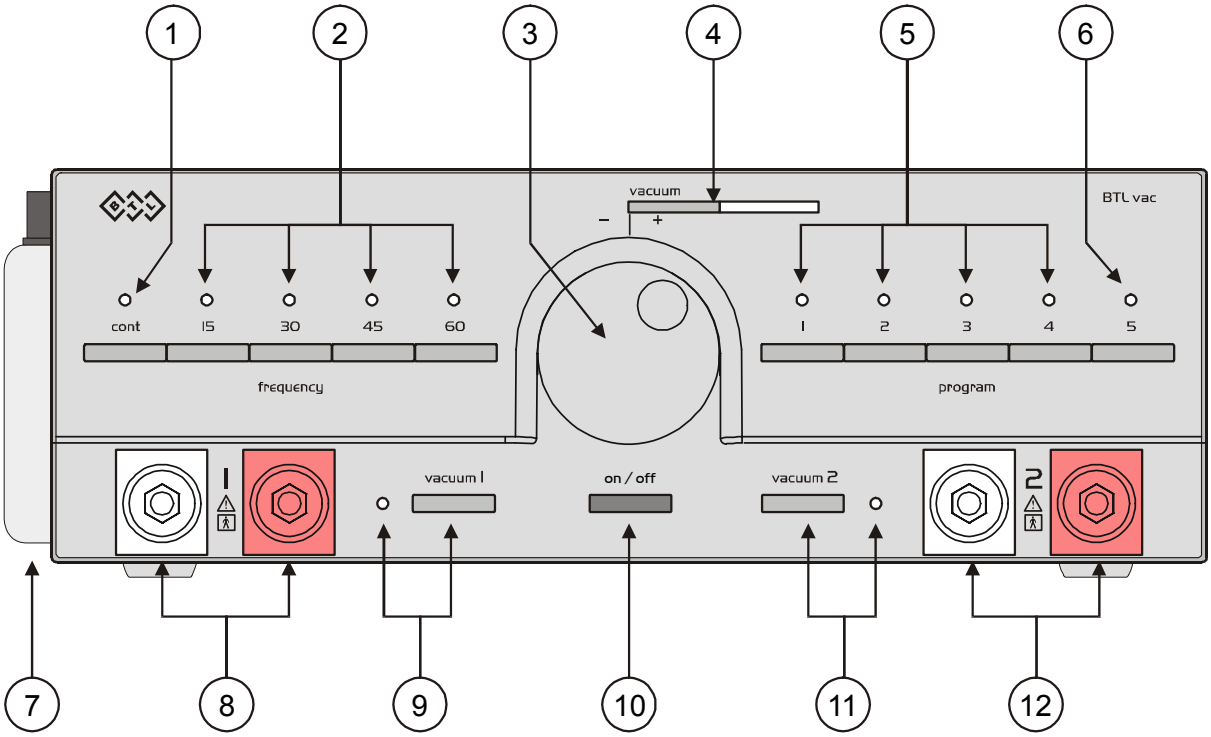
1 GENERAL CHARACTERISTICS

The **BTL vac** is a vacuum unit for application of electrotherapy currents by suction cup electrodes. Adjustable vacuum pressure ensures simple and convenient attachment of patient electrodes, especially on the parts of body hard to reach with flat rubber electrodes. Moreover, the pulse mode provides mechanical massage of the tissue, improves body metabolism and increases blood supply.

The **BTL vac** has two independent outputs and operates in both continuous and pulse mode. The unit has four pre-defined programs to combine various pulse frequencies, and a special program to control vacuum unit directly by the electrotherapy unit.

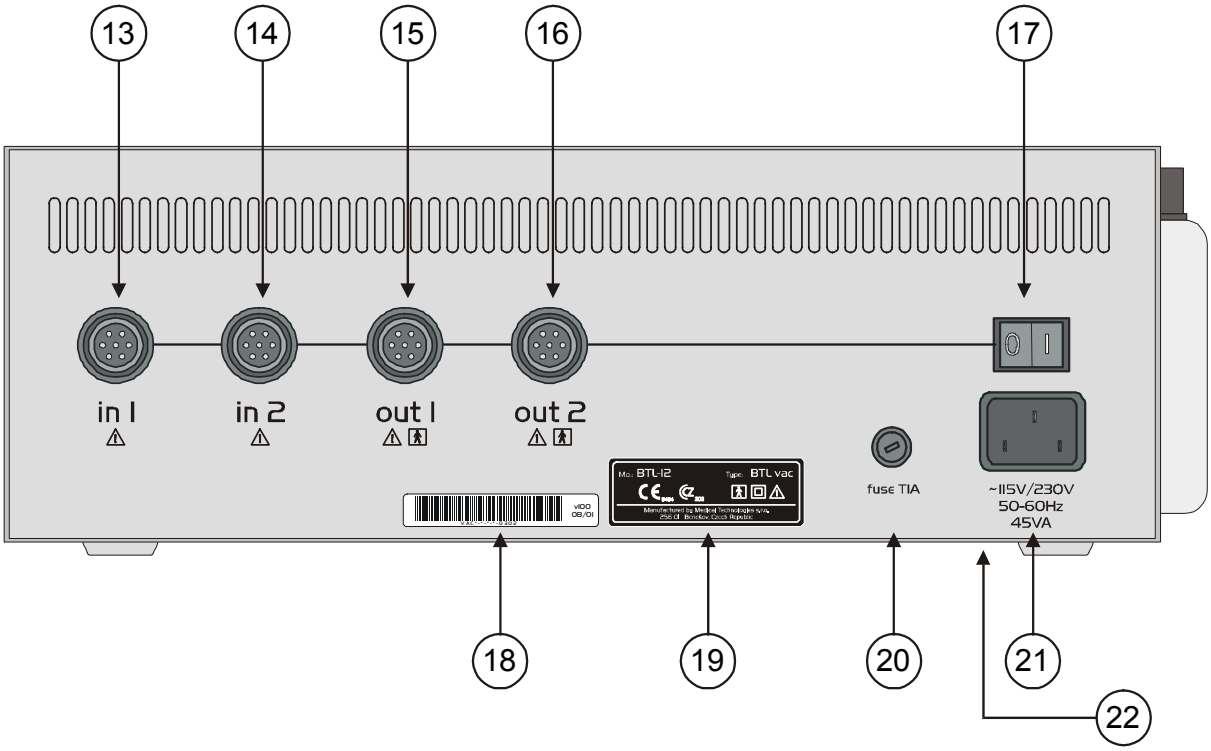
2 INSTRUCTIONS FOR USE

2.1 FRONT VIEW



1 **cont** button to select continuous mode (indicated by the pilot light)
2 buttons **15, 30, 45, 60** to select pulse mode (15, 30, 45 or 60 pulses per minute - indicated by the pilot light)
3 **vacuum** knob to set vacuum pressure
4 horizontal bar graph to display changes in vacuum pressure
5 buttons **1,2,3,4** to select massage program (selection indicated by the pilot light)
6 **program 5** button to control vacuum pressure by the electrotherapy unit
7 removable water container
8 channel 1 outputs for suction cups (red = anode +, white = cathode -)
9 **vacuum 1** button to switch electrotherapy channel 1 from classic to vacuum electrodes (indicated by the pilot light)
10 on / off switch (blue backlighting signals the ON status)
11 **vacuum 2** button to switch electrotherapy channel 2 from classic to vacuum electrodes (indicated by the pilot light)
12 channel 2 outputs for suction cups (red = anode +, white = cathode -)

2.2 REAR VIEW



13 connector for electrotherapy unit (channel 1)
14 connector for electrotherapy unit (channel 2)
15 connector for classic electrodes (channel 1)
16 connector for classic electrodes (channel 2)
17 mains switch – positions 0 / I
18 manufacture label with production number
19 type label
20 fuse box
21 mains plug
22 mains voltage switch 115 V / 230 V (on the bottom)

2.3 ASSEMBLY AND PUTTING INTO OPERATION

Inspect the box for damage and report any damage to carrier and distributor. Do not proceed with installation and assembly if box is damaged.

Unpack the equipment and place it on a stable horizontal surface suitable for the equipment's weight. Always position the unit out of direct sunlight. Always position the unit away from direct heat sources such as radiator or room heater. Cooling of the equipment is provided for by forced air circulation. Cooling vents must not be covered. Do not position the equipment on a soft surface which may obstruct air flow to the bottom cooling vents. Do not put any heat-producing devices or objects containing water or other liquid on the equipment. Do not place the equipment close to devices producing strong electromagnetic, electric or magnetic field (diathermy, X-rays, etc.), as this could affect equipment electronics.

Retain the original packaging to ensure maximum protection of the device during transportation.

Plug the device directly in the mains socket. Do not use any multi-connection extension cable or adapter.

Checking correct mains voltage:
Before first connection of the equipment to the mains check if the mains voltage switch (**17**) located on the rear panel is in the position corresponding to the local voltage standards, either in the "230V" or "115V" position.

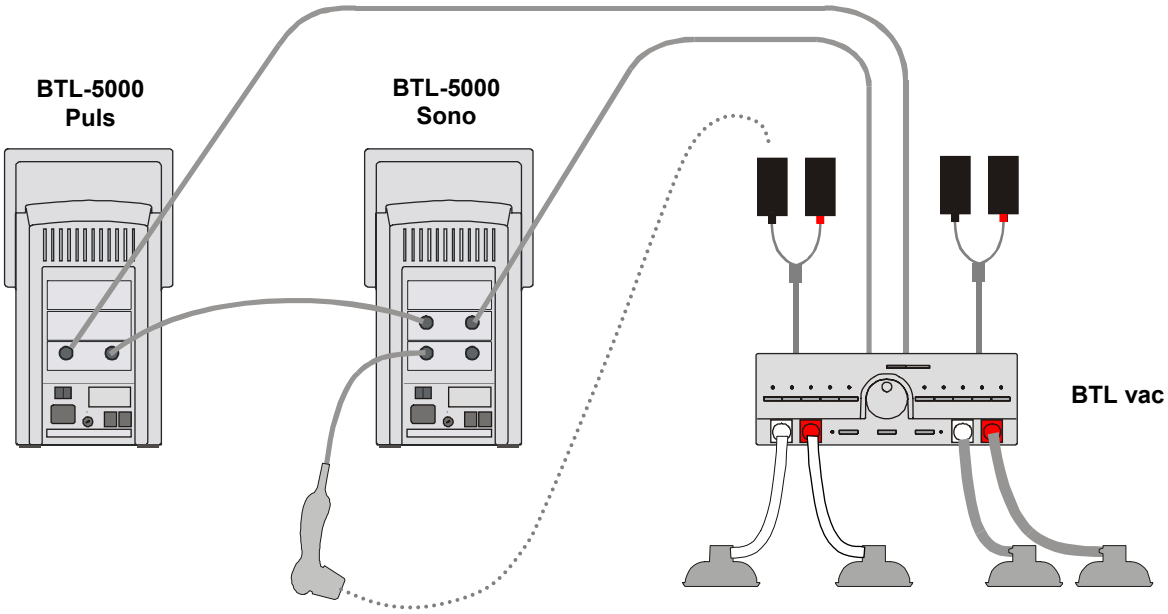
Removing adhesive tapes:
After unpacking remove adhesive tapes from the cover of the water container and from the top plexiglass. These tapes are only used for transport. Remove protective foil from the top plexiglass.

Switching the device on:
Plug the power supply into the mains socket and switch the **O**/ **I** rocker switch (**17**) on the rear panel to the "**I**" position. Press the **on/off** switch on the front panel. The ON status is indicated by the backlighting of the switch **(10)**.

2.4 INTERCONNECTION WITH ELECTROTHERAPY DEVICES

2.4.1 Connecting BTL vac to BTL-5000

To connect **BTL vac** with the **BTL-5000 Puls** and **Sono** devices**,** follow this diagram:



The same applies for the **BTL-5000 Puls** (the cable of the channel 2 leads directly to the **BTL vac**), and the **BTL-5000 Combi**.
We recommend that you connect channel 1 of electrotherapy with channel 1 of the **BTL vac**. Plug the patient cables with suction cups in the output connectors of the **BTL vac**. If connected properly, the white socket of the respective channel is cathode (-), the red one is anode (+).

2.4.2 Connecting BTL vac to BTL-06

Plug the interface cable to OUT A (channel 1 – in 1 **(13)**) and OUT B (channel 2 – in 2 **(14)**) sockets of the BTL-06 unit. Connect the patient cables of the BTL-06 to the connectors on the rear panel of the **BTL vac** –out 1 **(15)** and out 2 **(16)** outputs.
For the BTL-06 units manufactured prior to the year 2000, you must have a separate set of interface cables. See the leaflet enclosed with the set, or call your service agent.

2.4.3 Connecting BTL vac to Other Electrotherapy Devices

The **BTL vac** can be also used with the electrotherapy device BTL-05 and with devices of other manufacture. For connection, use the set of interface cables for **BTL vac** and electrotherapy devices. See the leaflet enclosed with the set, or call your service agent.

2.5 OPERATION

To switch on the equipment press the on/off button **(10)** on the front panel and hold it for approx. 2 seconds. The switch-on is indicated by the blue backlighting of the button and the short beep. Press the vacuum 1 **(9)** or vacuum 2 **(11)** button to connect the electrotherapy to the suction cup electrodes of the selected channel. The selection is indicated by the pilot lights **(9)** or **(11)**. Set the required vacuum pressure by the rotating knob **(3)**. A short beep signals that the vacuum pump has been switched on. The set value of the vacuum pressure is displayed on the graph **(4)**.

Moisten the sponges and attach the suction cup electrodes to the patient's body. Select the continuous (button **1**) or pulse (buttons **2, 5, 6**) mode (indicated by the pilot light). We recommend that you use continuous mode when fixing the electrodes.
Start the therapy on the electrotherapy device.
End the therapy: first switch off the electrotherapy device, then reduce the vacuum pressure by turning the knob **(3)** to the left. A short beep signals the end of operation.
To disconnect the suction electrodes of the selected channel press the vacuum 1 **(9)** or vacuum 2 **(11)** button. The switched-off diodes **(9)** or **(11)** indicate the connection of the classic electrodes.
To switch off the equipment hold the on/off button **(10)** for approx. 2 seconds. The backlight turns off.

For applications on thin and smooth skin set the vacuum pressure to approx. 40% of its maximum value to prevent excessive stress and potential skin damage.

2.5.1 Suction Cup Electrodes

The vacuum electrodes are supplied in three sizes – ∅ 30 mm, ∅ 60 mm and ∅ 90 mm.
The vacuum electrode sponges are supplied dry (after first soaking they "blow up") and impregnated by fungicide – wash them in tepid water before first use!
To moisten the sponges use tepid water or suitable therapeutic solution.
You can clean the electrodes using ordinary disinfectants. After disinfection rinse the electrodes and sponges in tepid water.

2.5.2 Water Container

The container **(7)** for water collected from the electrode sponges is placed on the side of the equipment. It is easily removable and dismountable. Its cleaning is easy: unscrew the black cover and pour the water out of the tank. You can clean the tank using ordinary disinfectants (first remove the inner cover with piston).
The water level in the tank is electronically checked. When the tank is full, an interrupted beeping is heard. Stop the therapy (first switch off the electrotherapy device) and turn the knob **(3)** to the left. Remove the tank, unscrew the cover, empty the tank and turn it back.

2.5.3 Changing Vacuum Pressure

2.5.3.1 Continuous Mode

The vacuum pressure is kept on the constant set value. Use when attaching electrodes to the skin. To select this mode press the button **(1)**.

2.5.3.2 Pulse Modes 15, 30, 45, 60

The vacuum pressure changes in regular pulses from the minimum value (approx. 10 kPa) to the set value. The number of pulses per minute (15, 30, 45, 60) can be selected by the buttons **(2)**.

2.5.3.3 Massage Programs 1, 2, 3, 4

The vacuum pressure changes in regular rhythmic sequences in which fast pulses alternate with slow ones. The length of the programs is 6 - 8 seconds. The rhythm of the programs ensures comfortable perception of the pressure changes. To select the the program 1 - 4 use the buttons **(5)**.

2.5.3.4 Controlling Vacuum Pressure by BTL-5000

The vacuum pressure is controlled directly by the electrotherapy device BTL-5000 Puls or BTL-5000 Combi. This mode is particularly convenient for long-term stimulation. When the electric surge is generated into the patient's body, the vacuum pressure automatically increases to ensure better contact of electrodes. During pause of surge the vacuum pressure decreases to the minimum (approx. 10 kPa) to reduce stress on the patient's skin. To select this program press the button **(6)**.

2.5.4 Washable Plate

The washable plastic plate on the top cover of the equipment is intended to shelf sponges etc. Wash with regular cleaners.

2.6 ACCESSORIES

2.6.1 Basic Accessories

BTL vac unit
mains cable
interface cables for connection to BTL-5000 (or BTL-06) – 2 pcs.
washable plate on the top cover – 1 pc.
patient vacuum cables – 4 pcs.
suction cup electrodes ∅ 60 mm, incl. sponges – 4 pcs.
needle for cleaning connectors – 1 pc.
spare fuse – 1 pc.
user's manual

2.6.2 Optional Accessories

suction cup electrodes ∅ 30 mm
sponges for electrodes ∅ 30 mm
suction cup electrodes ∅ 60 mm
sponges for electrodes ∅ 60 mm
suction cup electrodes ∅ 90 mm
sponges for electrodes ∅ 90 mm
set of interface cables for connection to electrotherapy devices
washable tray with holders for suction electrodes for combination with other electrotherapy devices

3 MAINTENANCE AND SAFETY

All maintenance and repairs must be carried out by authorized personnel only. The manufacturer bears no responsibility for the results of maintenance or repairs by unauthorized persons.

Safe operation of any item of medical equipment requires close attention to detail. Please check the following on a regular basis:

Power cord and plug - check for frays and kinks. Ensure that the insulation is not damaged in any way.

Wires, cables and electrodes - check for frays, cuts or tears in the insulation. Always route electrical cords and cables away from user or patient foot traffic areas where they could increase the chance of a tripping related accident.

Check the unit before each use to determine that all controls function normally.

Cleaning
To keep the device clean, do not store or use it in dusty environment and do not spill any liquid on the surface. To clean, turn the equipment off and unplug the power supply. Clean the unit with a damp cloth. Do not use abrasive materials. Do not use agents containing alcohol, ammonia, benzine, thinners. We recommend that you clean the accessories that come into contact with the patient after each treatment. Use appropriate agents. Rinse the sponges and electrodes in clean water after washing.
The patient's cables and electrodes should be at least one times per week disconnected from the unit and should be left to drying up.

No part of the equipment needs to be aseptic or sterilized.

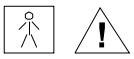
Fuse replacement
The fuse is located in the round black box on the rear panel. Make sure the mains switch (**17**) is in the "**0**" position. Unplug the power supply from the mains and from the equipment. Turn the segment of the fuse box to the left by a fitting screwdriver or coin in the slot. Remove the fuse. Insert a new fuse of the same rating and turn the box to the right.

Switching mains voltage
Before first connection of the equipment to the mains it is necessary to check if the mains voltage switch (**17**) is in the position corresponding to the correct voltage configuration, either in the "230V" or "115V" position. To change the voltage, make sure that the mains switch (**17**) is in the **0** position. Unplug the power supply from the mains as well as the equipment. Turn the segment of the switch by a fitting screwdriver or coin in the slot in the desired direction.

Transport and Storage
Keep the original packaging to ensure maximum protection of the device during transportation. Unplug the mains and accessories cables. Empty the water container. Store and transport in accordance with section **4 Technical Parameters**.

3.1 SAFETY

ATTENTION!
For the connectors marked by this label the consumed current or voltage can exceed safe values.



ATTENTION!
This system has no user serviceable parts or assemblies. Do not remove the instrument covers under any circumstances. Call your distributor for advice about any malfunction.

The device is equipped with a protection system that prevents connection of other accessories than supplied from the manufacturer.

The protection of the equipment is BF-type floating applied part.

Safety Precautions

- Read this manual thoroughly before operating the equipment.
- All staff should be instructed by the manufacturer or the distributor in the operation, maintenance and checking of the equipment and of all safety features and protocols.
- Make sure the electrical network in your facility is in compliance with valid norms.
- Check if the voltage switch located at the bottom of the equipment is switched to the correct voltage for your facility.
- Do not use this equipment in the presence of explosive gases and flammable anesthetics.
- Using this equipment in close proximity to other equipment may cause electromagnetic interference.
- Avoid the use of liquids in the immediate vicinity of this equipment since any liquid spilled onto the cabinet may cause serious damage to internal components.
- Inspect the equipment thoroughly before each use (loose cables, broken insulation of cables, display functions, pilot lights, controls, etc.).
- If the equipment shows any deviations from a normal operating situations, discontinue use and report the fault to authorized service personnel.
- Do not dismantle the equipment under any circumstances. Removal of protective covers implies the danger of electrical injury.
- Make sure that all materials and parts that come to direct contact with patient's skin comply with your national health standards.
- Simultaneous connection of the patient to a high-frequency surgical device may cause skin burning and damage the electrotherapy device.
- The connectors for accessories as well as the other connectors must not be used for connection of anything else than they are designed for, otherwise there is a danger of electric shock injury and serious damage to the equipment!
- The equipment does not use or produce any toxic substances during its operation, storage or transport.
- Exercise care when bringing the equipment from a cold environment to warm room. Do not plug it in the mains for at least 1 hour. Never expose this equipment to very warm or very cold climatic conditions.
- Before start of therapy check if all set parameters correspond to your intents.
- Never apply therapy on damaged skin!
- The time interval between switching the mains switch off and on must be at least 3 seconds.
- The equipment does not contain any toxic materials that would harm the environment.
- Use the equipment and the accessories only in accordance with the manual.
- Keep the equipment out of the reach of children.
- Always have the unit repaired by authorized service personnel.
- Always follow your local and national electrical, safety and healthy standards when using this equipment. Call your distributor for advice.

3.2 USEFUL ADDRESSES

The product is manufactured in accordance with the EU Medical Devices Directive by :

BTL Industries Ltd.
161 Cleveland Way
Stevenage
Hertfordshire, SG1 6BU United Kingdom
E-mail: sales@btlnet.com
http://www.btlnet.com

For service, please contact service department at service@btlnet.com.

3.3 WARRANTY

The Manufacturer of this product warrants the product to be free from defects in workmanship and material for a period of twelve months after the date of shipment from the factory. This warranty excludes any disposable items and accessories, including, but not limited to cables or leads, power cords and electrodes. The manufacturer agrees to correct such defects without charge, or at its option to replace the item with a comparable model. To register and be eligible for warranty service, you must send or fax the fully completed warranty registration form within 30 days of installation. All costs of shipment are the responsibility of the purchaser. Damage to any part such as by accident or misuse or improper installation or by use of any accessories or abrasive material not produced by the Manufacturer is not covered by this warranty. Because of varying climatic conditions, this warranty does not cover any changes in finish, including rusting, pitting, corrosion, tarnishing or peeling. Servicing performed by unauthorized persons render this warranty invalid. There is no other express warranty. The Manufacturer hereby disclaims any and all warranties, including but not limited to, those of merchantability and fitness for a particular purpose to the extent permitted by law. The duration of any implied warranty which cannot be disclaimed is limited to the time period as specified in the express warranty. The Manufacturer shall not be liable for incidental, consequential, or special damages arising out of, or in connection with product use or performance except as may be otherwise accorded by law.

This warranty may differ from the warranty terms and conditions provided by your supplier and by applicable laws in your country.

4 TECHNICAL PARAMETERS

Name of the equipment	vacuum unit **BTL vac**
Operating conditions	
ambient temperature	+ 10 °C to + 40 °C
relative humidity	30 % to 75 %
atmospheric pressure	700 hPa to 1060 hPa
position	horizontal – on legs
type of operation	continuous
Transport and storage conditions	
ambient temperature	- 10 °C to + 55 °C
relative humidity	25 % to 85 %
atmospheric pressure	650 hPa to 1100 hPa
position	any (if without water)
time max.	1 year
additional conditions	transport only in the supplied packing
Power supply	
input max.	45 VA
voltage	AC 100V to 126V (115V nominal) AC 198V to 252V (230V nominal)
frequency	50 – 60 Hz
equipment protection class according to IEC 536, EN 33 0600	II
external exchangeable fuse	T1A / 250V, tube fuse 5x20mm, according to IEC 127-2
mains switch according to IEC 601-1	on the rear side, positions 0 / I
power switch	on the front panel, labelled ON/OFF
Design	
weight – device only	6.8 kg
weight – including cables	7.8 kg
dimensions (l x w x h)	320 x 305 x 115 mm
expected lifetime	10 years
covering grade according to EN 60529	IP20

Adjustable Values

Vacuum pressure

range	10 - 50 kPa (0.1 – 0.5 bar)
step of setting	continuous

Pulses

selection from the values:	15, 30, 45, 60 pulses/min

Massage programs

program 1	preset
program 2	preset
program 3	preset
program 4	preset
program 5	controlled by the BTL-5000 device

Outputs/Inputs

number of independent therapies	2

Accuracy of adjustable values

vacuum pressure	± 30 %
pulse frequency	± 5 %

Classification

type of applied part according to IEC 601-1	BF
class according to MDD 93/42/EEC	IIb

Applicable Standards

No.	Name	IEC, EN, ISO, MDD
1	Medical electrical equipment Part 1: General requirements for safety	IEC 601-1
2	Amendments to IEC 601-1	A2, A11, A12
3	Medical electrical equipment Part 1: General requirements for safety 1.Collateral standard: Safety requirements for medical electrical systems	IEC 60601-1-1
4	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility. Requirements and tests	IEC 601-1-2
5	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011
6	Medical electrical equipment Part 1: General requirements for safety 4.Collateral standard: Programmable electrical medical systems	IEC 601-1-4
7	Medical devices - Risk Analysis	EN 1441
8	Biological evaluation of medical devices - Part 1: Evaluation and testing	ISO 10 993-1
9	The Medical Devices Directive 93/42/EEC	MDD 93/42/EEC

This product is manufactured in accordance with the EU Medical Devices Directive by:

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